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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,853	09/29/2006	Jiabing Wang	21492P	3712

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EXAMINER	
PIHONAK, SARAH	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
05/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,853	WANG ET AL.	
	Examiner	Art Unit	
	SARAH PIHONAK	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11,14-16,19-21 and 32-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-11,14-16,19-21 and 32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of PCT/US05/11537, filed on 4/4/2005.

Priority

This application claims priority to Provisional Application No. 60/560385, filed on 4/8/2004.

Response to Remarks

1. Applicant's arguments filed 2/15/2010, regarding the rejection of claims 1, 5-11, 14-15, and 19-21 under 35 USC 103(a) have been fully considered but they are not persuasive. The Applicants have argued that the claimed compounds would not have been prima facie obvious to one of ordinary skill in the art over Durette et. al., in view of Audia et. al., because the claimed compounds are not homologous to those taught by Durette et. al. The Applicants have maintained that the replacement of hydrogen for a methyl does not result in a homologous relationship between the claimed compounds and the compounds taught by Durette et al.; the reference of Rasmussen et. al., J. Med. Chem., 29, pp. 2298-2315, (1986), was previously submitted by the Applicants regarding this statement. However, as discussed previously, the substituted position of the compounds discussed in Rasmussen et. al. concerns the nitrogen position of the ring, and not the carbon atom to which R^4 is attached, as claimed. A carbon position on a ring is not equivalent to a nitrogen substituted position, due to differences in electron-donating properties between these atoms. The reference of Rasmussen et. al. presents results which show the differences between methyl and hydrogen substitution on the nitrogen position of the ring. As this position would not have been thought to be

equivalent to a carbon position of the ring, a comparison between the results of Rasmussen et. al. and the claimed compounds is not accurate. The Applicants have stated that the submission that the substitution of hydrogen for a methyl group is presumptuous and not valid, due to the evidence provided by Rasmussen et. al. The examiner respectfully disagrees. While the Applicants have shown through Rasmussen et. al. that hydrogen and methyl are not equivalent substituents on a nitrogen position, a nitrogen position is not equivalent to a carbon position. Therefore, as Rasmussen et. al. presents results regarding the substitution differences on a nitrogen position of the ring, there is no evidence to support that such differences would apply to a carbon position on the ring structure. The rejection was proper and is maintained, for reasons of record. For Applicants' convenience, this rejection will be reiterated in the office action.

2. Regarding the rejection of claims 1, 5-11, 14-15, and 19 under 35 USC 103(a) as being obvious over Graham et. al., in view of Audia et. al., the Applicants have reiterated their arguments as stated for the rejection under 35 USC 103(a) over Durette et. al. As discussed supra, Applicants arguments have been fully considered but are found unpersuasive, as Rasmussen et. al. shows the differences in hydrogen and methyl substituents on a nitrogen position of the ring structure, and not carbon. A carbon position on the ring structure is not equivalent to a nitrogen position. Therefore, this rejection is also maintained, for reasons of record, and will be restated in the office action.

3. Applicant's arguments, filed 2/15/2010, with respect to the rejection of claims 1, 5-11, 14-15, and 19-21 under 35 USC 112, second paragraph have been fully

considered and are persuasive. The claims have been amended to remove substituents drawn to position R^6. The rejection of 35 USC 112, second paragraph over claims 1, 5-11, 14-15, and 19-21 has been withdrawn.

4. Applicants' arguments regarding the rejection of claims 1 and 5-8 for obviousness type double patenting have been fully considered, but are not found persuasive. With regards to these rejections, Applicants have asserted that the claimed compounds are not obvious over US Patent Nos. 7,482,357 and 7,696,217 (formerly referred to as Application No. 10/557229), as Rasmussen et. al. teaches that the methyl and hydrogen substituents on a nitrogen position of the ring structure are not homologous. As discussed previously, this argument is not found persuasive. The rejections for obviousness type double patenting are maintained, for reasons of record. A modified rejection has been made over claims 1 and 5-8 over US Patent No. 7,696,217, in view of the allowance of Application 10/557229. Additionally, claim 16, which was previously indicated as allowable, is rejected in this office action, as it is drawn to the rejected species, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, N-(pyridin-2-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, and N-(pyridin-3-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide. Accordingly, this action is made NON-FINAL.

5. New claims 32-40 have been added by the Applicants. As they do not introduce new matter, these claims were also examined. A new rejection under 35 USC 112, second paragraph has been made over new claims 32-40, which will be explained further in the office action.

6. In the reply filed on 2/15/2010, Applicants have stated that claims 20-21 have been cancelled. However, in the amended claim set filed on 2/15/2010, claims 20-21 do not appear to have been cancelled. Therefore, the rejections over claims 20-21 are maintained.

7. Claims 1, 5-11, 14-16, 19-21, and 32-40 were examined.

8. Claims 1, 5-11, 14-16, 19-21, and 32-40 are rejected.

Claim Rejections-35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

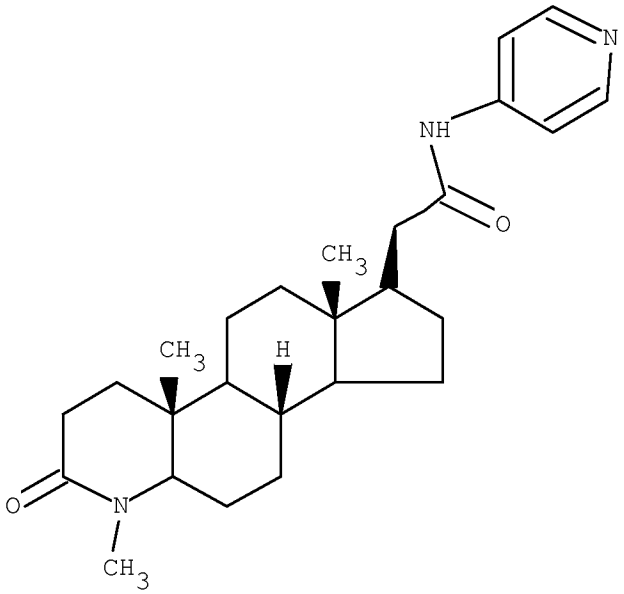
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 5-11, 14-16, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durette et. al., US Patent No. 5,693,809, in view of Audia et. al., US Patent No. 5,670,514.

13. Durette et. al. discloses a compound, N-(pyridin-4-yl)-4-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide (column 259, Table 9, compound 7). This compound, which will be referred to hereafter as 'compound 7', is shown below:



The substituents of compound 7, as taught by Durette et. al., correspond to the structure of formula (I) as follows: R^1=CH_3, R^2=H, R^3=(pyridin-4-yl), R^4=H, X=H, Y=H, a=single bond, and b=single bond. Durette et. al. teaches that compound 7 and other compounds act as 5α-reductase inhibitors, which are useful in treating conditions

associated with excess androgenic activity (column 1, lines 19-38, and column 2, lines 37-45). Durette et. al. also teaches that the compounds are present in a pharmaceutical composition, in a pharmaceutically acceptable carrier (column 272, lines 25-28, and column 273, lines 32-55).

Compound 7, as taught by Durette et. al., and the species of formula (I) of the instant application, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, are nearly identical. The only difference between the two compounds is that for compound 7, the R^4 substituent is H; for the instantly cited species of formula (I), R^4=CH_3. It is also known in the art that the substitution of a methyl group for hydrogen would be obvious, as they are considered homologues due to their structural similarity. Therefore, compound 7 of Durette et. al. and the instantly claimed species of formula (I), N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, are obvious variants of each other, and one of ordinary skill in the art would have been motivated, at the time of the invention, to substitute a methyl group for hydrogen at the R^4 substituent of compound 7 to arrive at the instantly claimed species. The substitution of a methyl group for hydrogen on a known compound does not render the modification patentable, in the absence of unexpected or non-obvious results, *In re Lincoln*, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942); *In re Druey*, 319 F.2d 237, 138 U.S.P.Q. 39 (C.C.P.A. 1963); *In re Lohr*, 317 F.2d 388, 137 U.S.P.Q. 548 (C.C.P.A. 1963); *In re Hoehsema*, 399 F.2d 269, 158 U.S.P.Q. 598 (C.C.P.A. 1968); *In re Wood*, 582 F.2d 638, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *In re Hoke*, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.P.A.

1977); *Ex parte Fauque*, 121 U.S.P.Q. 425 (P.O.B.A. 1954); *Ex parte Henkel*, 130 U.S.P.Q. 474, (P.O.B.A. 1960).

Durette et. al. does not explicitly teach that compound 7 and similar derivatives are combined with additional active agents, such as alendronate.

Audia et. al. teaches that bone loss can be reduced with 5α-reductase inhibition (column 2, lines 32-36). Audia et. al. particularly teaches that alendronate (as the sodium salt) is effective in reducing bone loss by inhibiting bone resorption (column 143, lines 37-50).

Compound 7 is taught by Durette et. al. as capable of inhibiting 5α-reductase activity (column 259, Table 9, compound 7, and column 2, lines 37-45). Audia et. al. teaches that 5α-reductase enzyme inhibition reduces bone loss (column 2, lines 32-36). The instantly claimed species, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, which is a methyl analog of the compound taught by Durette et. al., would also have been expected, by one of ordinary skill in the art, to reduce bone loss, as homologous compounds are expected to have similar chemical and physical properties, absent unexpected results. Audia et. al. also teaches that alendronate is effective in decreasing bone loss (column 143, lines 37-50). The combination of two compounds used for the same purpose, such as reducing bone loss, would have been prima facie obvious to one of ordinary skill in the art, at the time of the invention. Therefore, one of ordinary skill in the art would have been motivated to combine instantly claimed methyl analog of compound 7 with alendronate in a composition, as both active agents would have been expected to function in minimizing bone loss. It

would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to combine the instantly claimed methyl analog of compound 7, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, with alendronate, as Durette et. al. teaches that compound 7 reduces 5α-reductase enzyme activity, and Audia et. al. teaches that 5α-reductase inhibitors such as alendronate function to minimize bone loss. The methyl analog of compound 7, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5α-androst-17ß-acetamide, would also have been expected to reduce bone loss, as it is a methyl homolog of the compound taught by Durette et. al.

Claim Rejections-35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

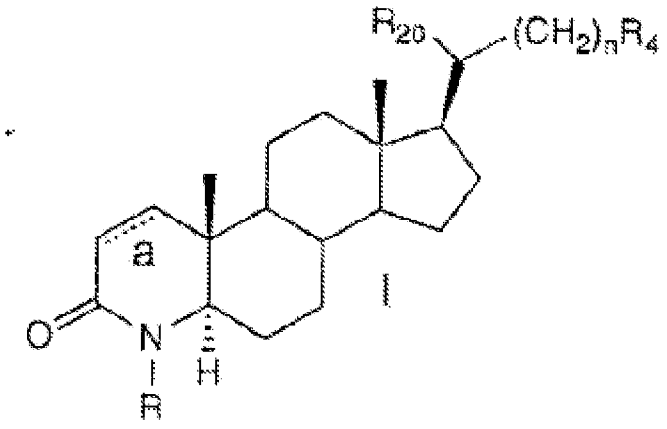
15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1, 5-11, 14-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et. al., WO 93/23051 patent publication, in view of Audia et. al., US Patent No. 5,670,514. The reference of Graham et. al. was presented on the Information Disclosure Statement.

The claims are drawn to a compound of formula (I), as defined by the chemical structure shown below:



Graham et. al. teaches compounds of the same core structure as the claimed compounds, with the following defined substituents of the formula shown above: R_{20}=H, or methyl; n=0; R_4=CONH-(Me)-pyridyl; R=Me or ethyl; a=single bond. These substituents correspond to the instantly claimed structure of formula (I) as follows: R^1=methyl or ethyl; b=single bond; X=H; or methyl; R^2=methyl; R^4=pyridinyl (p. 3, line 15-p. 4, line 32; p. 31, compound 7a; p. 32, compounds 15a & 15b) . The only difference between the compounds disclosed by Graham et. al. and the instantly claimed compounds is that the R^4 position for the claimed compounds is occupied by a methyl group, etc.; this position for the compounds taught by Graham et. al. is occupied by hydrogen. It is also known in the art that the substitution of a methyl group for hydrogen would be obvious, as they are considered homologues due to their structural similarity. The substitution of a methyl group for hydrogen on a known compound does not render the modification patentable, in the absence of unexpected or non-obvious results, *In re Lincoln*, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942); *In re Druey*, 319 F.2d 237, 138 U.S.P.Q. 39 (C.C.P.A. 1963); *In re Lohr*, 317 F.2d 388, 137 U.S.P.Q. 548 (C.C.P.A. 1963); *In re Hoehsema*, 399 F.2d 269, 158 U.S.P.Q. 598 (C.C.P.A. 1968); *In re Wood*, 582 F.2d 638, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *In re Hoke*, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.P.A. 1977); *Ex parte Fauque*, 121 U.S.P.Q. 425 (P.O.B.A. 1954); *Ex parte Henkel*, 130 U.S.P.Q. 474, (P.O.B.A. 1960). Graham et. al. also teaches the compounds along with pharmaceutical acceptable excipients and diluents (p. 44, lines 22-28). Therefore, the compounds and compositions taught by Graham et. al. are obvious variants of the claimed compounds. Graham et. al. also

teaches that the compounds are 5α-reductase inhibitors, and are useful for treating conditions associated with hyperandrogenic stimulation (Abstract; p. 1, lines 28-33). Graham et. al. does not explicitly teach that the compounds are combined with additional active agents such as alendronate.

Audia et. al. teaches that bone loss can be reduced with 5α-reductase inhibition (column 2, lines 32-36). Audia et. al. particularly teaches that alendronate (as the sodium salt) is effective in reducing bone loss by inhibiting bone resorption (column 143, lines 37-50).

Audia et. al. teaches that 5α-reductase enzyme inhibition reduces bone loss (column 2, lines 32-36). The instantly claimed compounds of formula I, which are methyl analogs of the compounds taught by Graham et. al., would also have been expected, by one of ordinary skill in the art, to reduce bone loss, as homologous compounds are expected to have similar chemical and physical properties, absent unexpected results. Audia et. al. also teaches that alendronate is effective in decreasing bone loss (column 143, lines 37-50). The combination of two compounds used for the same purpose, such as reducing bone loss, would have been prima facie obvious to one of ordinary skill in the art, at the time of the invention. Therefore, one of ordinary skill in the art would have been motivated to combine the claimed methyl analogs of the compounds taught by Graham et. al. with alendronate in a composition, as both active agents would have been expected to function in minimizing bone loss. It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to combine the instantly claimed methyl analogs of the compounds taught by Graham et. al., with

alendronate, as Graham et. al. teaches that the compounds reduce 5α-reductase enzyme activity, and Audia et. al. teaches that 5α-reductase inhibitors such as alendronate function to minimize bone loss. The claimed compounds of formula I would also have been expected to reduce bone loss, as they are methyl homologs of the compound taught by Graham et. al., and therefore would have been expected to possess similar chemical and physical properties.

Claim Rejections-Obviousness Type Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

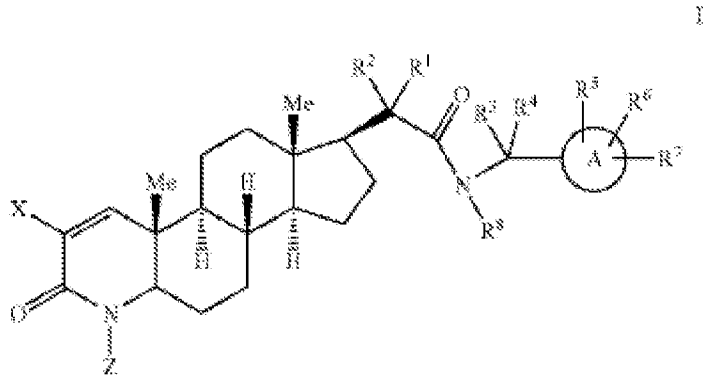
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1 and 5-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,482,357. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the compounds claimed in the instant application and the US 7,482,357 patent are obvious variants of each other.

20. The instant application cites compounds of formula (I), which share the same backbone as the compounds cited by claim 1 of the US ‘357 patent. The compounds of formula I claimed by the US '357 patent are shown below:



For compounds of formula I above, X=H or halogen; Z=hydrogen, C_{1-3} alkyl, etc.; R^1=hydrogen, C_{1-3} alkyl, halogen, hydroxyl, etc.; R^2= H, halogen, hydroxyl, etc.; R^8=hydrogen, etc.; R^3=hydrogen, etc.; R^4=hydrogen, etc.; A=pyridinyl or quinolyl, R^5-R^7=H, etc. These compounds overlap with the instantly claimed compounds of formula (I), as for formula (I), R^3=$(CH_2)_n$-heteroaryl, in which n=1-2; R^2=H; X=H; Y=H; R^1=C_{1-3} alkyl; a= single bond; b=double bond. The only difference between the corresponding compounds disclosed in claim 1 of the US ‘357 patent and the instant compounds of formula (I) is that, for formula (I), R^4=CH_3, etc. This position is occupied by a hydrogen for formula I compounds disclosed by the US ‘357 patent. However, the substitution of a methyl as the R^4 substituent over hydrogen would have been obvious to one of ordinary

skill in the art, as the groups are considered homologues, due to their structural similarity. Therefore, the compounds disclosed in claim 1 of the US '357 patent and the instant claims 1-2, and 5-8 overlap and are obvious variants of each other.

Claim Rejections-Obviousness Type Double Patenting

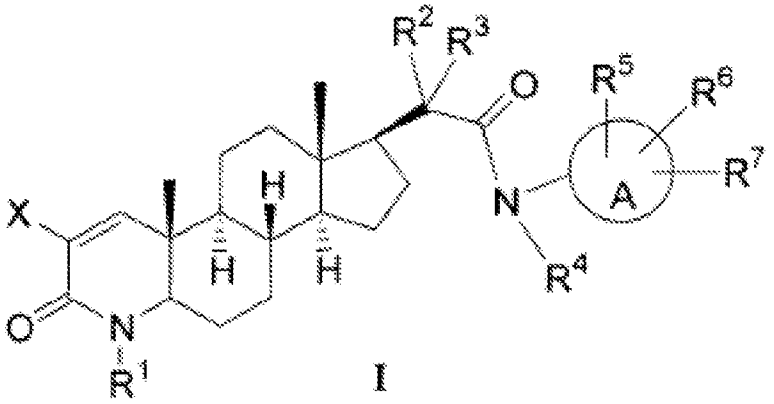
21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1 and 5-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, and 8-9 of US Patent No. 7,696,217 (formerly Application No. 10/557229). Although the conflicting claims are not identical, they are not patentably distinct from each other because species of compounds of formula I cited by the copending application are obvious variants of compounds cited in the instant application.

23. The instant application cites compounds of formula (I) which share the same carbon backbone as compounds of formula I disclosed by US Patent No. 7,696,217. The structure of formula I as disclosed by the instant application is shown below:



I

The substituents of formula I which correspond to that of the instantly cited formula (I) are as follows: R^1=H, C_{1-3} alkyl, etc.; R^2=H, halogen, etc.; R^3=H, halogen, etc.; R^4=H, etc.; R^5-R^7=H, halogen, etc.; A=pyridinyl; X=hydrogen, etc. For compounds of the instantly cited formula (I), A=pyridinyl; R^1=C_{1-3} alkyl; X=H; R^2=H; R^3=H; and R^5-R^7=H, halogen, etc. The only difference between compounds of formula I as disclosed in the copending application and compounds of formula (I) in the instant application is that the R^4 substituent in the instantly cited application is occupied by a methyl or another substituent. This corresponding position is occupied by hydrogen for formula I. However, the replacement of hydrogen for a methyl group would have been routine and obvious for one of ordinary skill in the art, as the groups are structurally similar to each

other. As such, the compounds claimed by the copending application of formula I and of formula (I) of the instant application are obvious variants of each other.

Claim Rejections-35 USC § 112

24. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. Claims 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is drawn to the compound of claim 32, where R^4 is chosen as halogen, C_{1-6} alkyl, and $(CH_2)_n$-phenyl, wherein C_{1-6} alkyl, and $(CH_2)_n$-phenyl is optionally substituted with one or more substituents. However, in claim 32, R^4 is substituted with one or more substituents; optional substitution of R^4, in which R^4 may not be substituted, is not claimed. As claim 37 is drawn to the compounds in which R^4 is optionally substituted, it is not certain as to which compounds are being claimed, those in which R^4 may be unsubstituted or those in which R^4 is substituted with one or more of the claimed substituents. As such the claim is indefinite.

Claim 32 contains language in which R^6 is defined as halogen, hydroxyl, $CONH_2$, etc. However, substituent R^6 is not shown on the ring of formula (I), nor is it defined by any other variables. Therefore, it is not certain what is meant by the position R^6. As such, the claim is indefinite. Claims 33-40, which are dependent claims of claim 32, are also rejected for this reason.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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S.P.

/SREENI PADMANABHAN/

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